DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020895

INFORMATION REQUEST

Pfizer, Inc.
Attention: Marsa Hatfield
Director, Worldwide Safety & Regulatory
445 Eastern Point Road
Groton, CT 06340

Dear Ms. Hatfield:

Please refer to your New Drug Application (NDA), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for VIAGRA® (sildenafil citrate) tablets.

We have become aware of an increasing number of post-marketing reports of melanoma in association with the use of phosphodiesterase Type 5 inhibitors (PDE5i), including Viagra. Based on this information, we have begun a review of this matter under Tracked Safety Issue (TSI) #1579.

In order to continue our review, we request the following information by July 15, 2016:

Conduct a search of your clinical trial databases to identify all adverse event (AE) reports of melanoma in clinical trials of Viagra using all Preferred Terms (PT) under the High Level Term (HLT) Skin Melanomas; and all PT under the HLT Ocular Melanoma in MedDRA 19.0 or in the MedDRA version used for each study. If different MedDRA terms were used in different studies, harmonize those terms to facilitate data interpretation.

Using the cases identified, provide results from these analyses:

1. Compare melanoma incidence rates between drug and placebo, as well as between drug and active comparator, when available. Provide 95% confidence intervals and relative risk assessments.

2. Provide an assessment of melanoma incidence rates by dose, duration, and length of time from Viagra exposure to AE report.

3. Compare melanoma incidence rates between daily use and ad lib (prn) use of Viagra.

4. In studies with no control arm, compare melanoma incidence rates to demographically-matched SEER melanoma incidence rates.

5. Identify cases in which more than one PDE5i was used by the same subject. Perform analyses with these subjects included and excluded.

6. Identify cases in which baseline risk factors for melanoma were reported. Perform analyses with these subjects included and excluded

7. Perform analyses 1 - 6 for the incidence of basal cell carcinoma identified as AEs in clinical trials of Viagra.

In addition, provide an overall evaluation of the data and conclusion about the risk of melanoma associated with use of Viagra.

If you have any questions, call Meredith Alpert, MS, Safety Regulatory Project Manager, at (301) 796-1218.

Sincerely,

{See appended electronic signature page}

Christine P. Nguyen, MD
Deputy Director for Safety
Division of Bone, Reproductive and Urologic Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

MEREDITH ALPERT
06/03/2016

CHRISTINE P NGUYEN
06/03/2016